HARVARD SCHOOL OF PUBLIC HEALTH

Human Subjects Committee
Ichiro Kawachi, M.D., Ph.D., Co-Chair
Michelle Mello, J.D., Ph.D., M.Phil., Co-Chair

1552 Tremont Street
Boston, Massachusetts 02120
Tel. (617) 384-5480 fax (617) 384-5484
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January 28, 2008

Dr. Petros Koutrakis
Harvard School of Public Health
Landmark Center, Room 410A
401 Park Drive
Boston, MA 02215

RE: IRB Authorization Agreement
Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures
PI: Dr. Petros Koutrakis
HSC Protocol #P15459-101
Reviewing Institution's Protocol #05-143

Dear Dr. Koutrakis:

In accordance with your request, we have obtained an IRB Authorization Agreement (the "Agreement") between St. Michael's Hospital and the Harvard School of Public Health (HSPH). This status was effective on January 14, 2008. We have enclosed a copy of the fully executed Agreement for your records.

Under this Agreement, HSPH relies on St. Michael's Hospital for IRB review for the above-referenced study. Please be sure to inform yourself of that institution's IRB requirements and be sure to comply with all applicable rules and policies.

Please note your important ongoing obligations to our office:

1. You must forward a copy of the reapproval notice from the reviewing IRB to our office within 30 days of receipt. You may fax the notice to us at (617) 384-5484.

2. You must forward a copy of any amendment approval notices by the reviewing IRB, from the previous approval, period to our office along with the reapproval notice (see above). You may fax these to us at (617) 384-5484. Alternatively, you may fax amendment approval notices to us on a rolling basis.

3. You must forward a copy of any notice of a lapse in approval from the reviewing IRB within 30 days of receipt. You may fax the notice to us at (617) 384-5484.

4. In the unlikely event that the reviewing IRB makes a determination of serious or continuing non-compliance by you (which must be reported to the U.S. Office for Human Research Protections), or suspends or disapproves this study, you must notify our office within two business days.

5. You must comply with HSC requirements for ongoing training in human subjects protections.

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6. Please review your obligations as set forth in the enclosed copy of the IRB Authorization Agreement at least once a year and communicate them to your research staff.

If you have any questions, please don't hesitate to contact me. Thank you for your commitment to the welfare of human participants in your research.

Sincerely,

[redacted]

Enclosure